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DATE: June 12, 2002

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TO: Examiner R. Covington
FAX NUMBER: (703) 308-7921 (Group Art Unit: 1625)
FROM: Wendy Lei Hsu, Patent Counsel/Reg. No. 42,794
RE: Application No. 08/916,527
DOCKET : For: Neuropeptide-Y Ligands
0035-01-US

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(s) Wendy Lei Hsu
Wendy Lei Hsu

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re U.S. Patent Application of:**Hong et al.**

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Examiner: R. Covington**Serial No.: 08/916,527**

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Group Art Unit: 1625**Filed: August 22, 1997**

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For: NEUROPEPTIDE-Y LIGANDS

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Atty. Docket No.: 0035-01

REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. § 1.111

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

This is a response to the Office Action mailed March 12, 2002.

Claims 11-25 are pending in this application. Claims 11-25 are rejected under 35 U.S.C. 112, first paragraph, for alleged lack of enablement. In rejecting the claims, the Examiner asserts that the specification lacks enablement for heterocyclic containing derivatives, such as, N-heterocyclic derivatives, and that there is insufficient enabling disclosure to support the terms heteroaryl R¹, R³, R⁵, R⁶, R⁷, R⁹, R¹¹ and Q derivatives. The Examiner further asserts that the Applicant has not disclosed any working examples which would demonstrate, or guide, one skilled in the art as to how to obtain the N-heterocyclic derivatives. Applicant respectfully disagrees.

It is well established that the first paragraph of Section 112 of the patent statute requires only objective enablement of the invention. How the teaching is set forth, either by the use of specific examples or broad terminology, is of no importance. *In re Marzocchi*, 169 U.S.P.Q. 367

(C.C.P.A. 1971). Accordingly, when rejecting a claim under the enablement requirement, it is the PTO who bears the initial burden of setting forth a reasonable explanation as to why he believes that the scope of protection is not adequately enabled. *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993). To properly assert a rejection on the grounds that the disclosure is not enabling, the Office Action must provide evidence or sound technical reasoning substantiating its position. Without a reason to doubt the truth of the statements made in the patent application, the application *must be considered enabling*. *Id.* The following statement from *In re Armbruster*, 512 F.2d 676, 677 (C.C.P.A. 1975) is noteworthy:

[It] is incumbent upon the Patent Office, whenever a rejection on this basis [lack of enablement] is made, to explain why it doubts the truth or accuracy of any statements in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

Applying these tenets to the present situation, the Office Action provides no objective evidence to support the opinion that the heterocyclic containing derivatives are not enabled by the specification. Significantly, the Office Action concedes that the specification is enabling for tetrahydrofuran heterocyclic moieties, but concludes that the additional heterocyclic containing derivatives encompassed by the claims are not enabled.

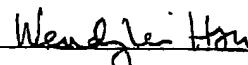
Contrary to the Examiner's assertion that the specification lacks guidance, Applicant especially submits that the specification provides ample guidance (pages 24-62) as to how to prepare the compounds containing heteroaryl substituents. Schemes I-IV provides synthesis schemes for the preparation of compounds containing heteroaryl derivatives, and Examples 1-2 in particular describes preparation disclosing heteroaryls in R⁹ and R¹⁰ (pages 40-41 and 48-49), R¹ (page 42-43 and 50-51) and Q (pages 44 and 52). Moreover, each of Examples 1-6 (pages 37-61) can be successfully modified by conventional methods known in the art, that is, by appropriate protection of interfering groups, by changing to alternative conventional reagents, or by routine modification of reaction conditions. For example, one skilled in the art would recognize that the R and Q groups listed on pages 40-44 and 48-52, are commercially available through distributors such as Sigma-Aldrich or can be readily synthesized by well-known literature methods. One skilled in the art would further recognize that the disclosed compounds

on pages 40-41 can be achieved by routine modification of the reaction in Example 1 (page 37) such that the 1,3-bis(aminomethyl)benzene starting reagent is replaced by a corresponding R group from pages 40-41 as starting reagent. Similarly, one skilled in the art would recognize that the compounds listed on pages 44 and 52 can be achieved by routine substitution of the 1,3-bis(aminomethyl)benzene starting reagent in Examples 3 and 5 (pages 53 and 58-59) with the corresponding Q group from page 44 or 52 as a starting reagent. The specification is replete with such examples, whereby routine modification of the synthesis scheme can provide the compounds of the invention. The Examiner's bare assertion of non-enablement is insufficient to support a *prima facie* case, for the assertion fails to take into account the skills and knowledge possessed by the ordinary worker in this art.

It is respectfully asserted that the Office Action inappropriately seeks to limit the Applicants to the aforementioned tetrahydrofuran heterocyclic moieties. However, only an enabling disclosure is required. M.P.E.P. § 2164.02. Accordingly, such a narrow characterization misinterprets the present invention in an effort to limit its scope, and fails to consider the genus as a whole, as is required by law. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

For the foregoing reasons, the Examiner's rejections of claims 11-25 under 35 U.S.C. 112 are in error, and their withdrawal is respectfully requested.

Respectfully submitted,



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Date: June 12, 2002

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